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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application

Appellant:	Shlomo Gabbay	Art Unit:	3738
Serial No.:	09/973,609	Examiner:	B. Pellegrino
Filed:	October 9, 2001		
Title:	IMPLANTATION SYSTEM FOR IMPLANTATION OF A HEART VALVE PROSTHESIS		

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SUPPLEMENTAL APPEAL BRIEF

Sir:

Following the Notification of Non-Compliant Appeal Brief issued on November 4, 2005 for the Appeal Brief filed on September 24, 2004, Appellant presents this Supplemental Appeal Brief to replace the currently pending Appeal Brief.

1. REAL PARTY IN INTEREST

The real party in interest is Shlomo Gabbay.

2. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

3. STATUS OF CLAIMS

Claims 1-47 were originally filed.

A preliminary amendment was filed in response to a verbal restriction requirement from Examiner Prebilic. The preliminary amendment cancelled claims 1 and 29-47, amended claims 2-17 to depend from claim 18, and added new claims 48-60.

In an Office Action dated July 2, 2003, Examiner Pellegrino issued a requirement to elect a species from the pending claims 2-28 and 48-60.

A response to the election requirement was filed on August 1, 2003. The response elected species VI, corresponding to claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 48, 49, 50, 51, 52, 53, 54, 5, 56, 57, 58, 59 and 60.

A Non-Final Office Action was mailed on October 22, 2003. The Office Action rejected claims 2-28 and 48-60.

A response to the Office Action dated October 22, 2003, was filed on January 20, 2004. The response amended claims 17, 18, 20, 27, 28, 49, 50, 51, 53-57, and 60 and cancelled claims 48, 58 and 59.

A Final Office Action was mailed on April 27, 2004. The Final Office Action rejected claims 2-28, 49, 50, 53-57 and 60, and objected to claims 51 and 52, indicating

that claims 51 and 52 would be allowable if rewritten in independent form, including all the limitations of their base claims and any intervening claims.

A response to the Final Office Action was filed via facsimile on June 28, 2004. The response amended claims 21, 22, 27, 28, 50, 51 and 53, cancelled claims 20 and 49, and argued that the rejections of claims 2-19, 21-28, 50-57 were improper.

A Notice of Appeal was filed on July 26, 2004 in response to the Final Office Action dated April 27, 2004.

An Advisory Action was mailed on July 26, 2004. The Advisory Action maintained the rejection of claims 2-28, 49, 50, 53-57 and 60 and stated that the amendments contained in the response filed on June 28, 2004, would not be entered. The Advisory Action further indicated that proposed or amended claims 21-28, 51 and 52 would be allowable if the non-allowable claims were cancelled.

In sum, independent claims 18, 20 and 50 and dependent claims 2-17, 19, 21-28, 49, 53-57 and 60 stand rejected, claims 51 and 52 stand objected to, and the rejection is appealed.

4. STATUS OF AMENDMENTS

A response was filed on June 28, 2004 subsequent to final rejection. The amendments contained in the response filed on June 28, 2004, were denied entry according to an Advisory Action that was mailed on July 26, 2004. The Advisory Action, indicated, however, that claims 21-28, 51 and 52 would be allowable if submitted in a separate timely filed amendment canceling the non-allowable claims. Appendix A submitted herewith contains a listing of claims in their form, as amended by Appellant's response of January 20, 2004.

Submitted herewith as Appendix B is a proposed amendment to claims 18, 50 and 53, which Appellant requests be entered before jurisdiction is transferred to the Board.

5. SUMMARY OF THE CLAIMED SUBJECT MATTER

a. Claim 18 (Independent)

The present invention relates to a heart valve prosthesis (10, 50, 100, 202, 300, 350, 470, 540, 570, 702, 748) in combination with an implanter (200, 700, 736). See page 2, lines 17+; page 5, lines 12+; page 9, lines 3+; page 11, line 4; page 12, lines 22-24; page 14, line 16+; page 15 lines 15+; page 18, lines 30+; page 21, lines 27+; page 23, lines 16+; page 26, lines 4+; page 28, lines 27+; and page 12, lines 22+; page 26, lines 4+; and page 27, lines 4+. The heart valve prosthesis (10, 50, 100, 202, 300, 350, 470,540, 570, 702, 748) may comprise a generally cylindrical support (14, 54, 80, 400, 420, 500, 572, 574, 752) extending between opposed ends thereof.

A plurality of support features (406, 428, 512, 578, 756 ; see also page 2, line 19; page 22, line 19; page 23, line 25+; page 29, lines 5+) extend generally axially between the opposed ends of the support and are interconnected so as to bias the support radially outwardly.

A valve (20, 52, 98, 472, 590, 754) is mounted within the support to define a supported valve (10, 50, 100, 202, 300, 350, 470, 540, 570, 702, 748). The valve (20, 52, 98, 472, 590, 754) can be a pulmonic animal heart valve. See page 6, lines 4-7; page 20, lines 10-11; page 23, lines 4-5; page 25, lines 11-12. The supported valve is deformable between a first condition and a second condition. The supported valve has a cross-sectional dimension in the second condition that is less than a cross-sectional dimension of the supported valve when in first condition, whereby implantation of the

supported valve is facilitated when in the second condition. See page 2, lines 27-30; page 6, lines 31+; page 21, lines 21+)

The implanter (200, 700, 736) includes an elongated cylindrical enclosure (208, 353, 704, 734) dimensioned and configured to receive the prosthesis when in the second condition. See Figs. 6A, 9A, 9B, 11, 19-22; and page 3, lines 1-6; page 10, lines 25+; page 12, lines 30+; page 15, lines 16+. The prosthesis is disposed within the cylindrical enclosure, such that an inner sidewall of the cylindrical enclosure maintains the prosthesis in the second condition. See page 3, lines 1-4; page 13, lines 15-18; 26, and page 26, lines 14-19.

b. Claim 17 (Depends from Claim 18)

The prosthesis (10, 50, 100, 202, 300, 350, 470, 540, 570, 702, 748) further can include comprising an outer sheath (130, 440) of a substantially biocompatible material that covers at least a substantial portion of the exposed parts of the support. See Figs. 7 and 8 and page 11, lines 25 – 27; page 20 lines 20-24.

c. Claim 53 (Depends from Claim 18)

The implanter (200, 700, 736) can also include a body portion (706) from which the cylindrical enclosure (208, 353, 704, 734) extends and terminates in an open end. See Fig. 19 and page 26, lines 29-31.

d. Claim 54 (Depends from Claim 53)

The cylindrical enclosure (208, 353, 704, 734) of the implanter (200, 700, 736) can have an inner diameter in a range from about 5 mm to about 15 mm, and the body portion (706) having a diameter that is greater than that of the cylindrical enclosure (208, 353, 704, 734). Page 27, lines 6–8.

e. **Claim 55 (Depends from Claim 53)**

A handle portion (712) can be attached to the body portion (706) at a substantially opposite end from which the cylindrical enclosure (208, 353, 704, 734) extends. See Fig. 19 and page 27 lines 14-16.

f. **Claim 56 (Depends from Claim 53)**

The cylindrical enclosure (208, 353, 704, 734) and body portion (706) of the implanter (200, 700, 736) can be substantially coaxial along a linear axis extending through the implanter (200, 700, 736). See Fig 19.

g. **Claim 50 (Independent)**

The present invention also relates to an implantation system (200, 700, 736), that can comprise an elongated cylindrical member (14, 54, 80, 400, 420, 500, 572, 574, 752) having spaced apart ends, at least one of the ends providing an opening. See Fig. 19 and page 26, lines 29-31.

A body portion (706) from which the cylindrical member (14, 54, 80, 400, 420, 500, 572, 574, 752) extends to terminate in the opening spaced apart from the body portion (706).

A heart valve prosthesis (10, 50, 100, 202, 300, 350, 470, 540, 570, 702, 748) including a generally cylindrical support (14, 54, 80, 400, 420, 500, 572, 574, 752) having axially spaced apart ends. The heart valve prosthesis (10, 50, 100, 202, 300, 350, 470, 540, 570, 702, 748) also includes a valve (20, 52, 98, 472, 590, 754) mounted within the support at a fixed axial position between the spaced apart ends of the support. The prosthesis (10, 50, 100, 202, 300, 350, 470, 540, 570, 702, 748) is deformable to a first condition in which the prosthesis has a reduced cross-sectional

dimension. The support is biased to expand the prosthesis (10, 50, 100, 202, 300, 350, 470, 540, 570, 702, 748) radially outwardly from the first condition to a second condition in which the prosthesis (10, 50, 100, 202, 300, 350, 470, 540, 570, 702, 748) has a cross-sectional dimension that is greater than the reduced cross-section dimension. See page 2, lines 27-30; page 6, lines 31+; page 21, lines 21+. The prosthesis (10, 50, 100, 202, 300, 350, 470, 540, 570, 702, 748) being mounted within the cylindrical member (14, 54, 80, 400, 420, 500, 572, 574, 752) in the first condition.

A plunger (210, 716, 750) is operative to traverse at least part of the cylindrical member (14, 54, 80, 400, 420, 500, 572, 574, 752) and to urge the prosthesis (10, 50, 100, 202, 300, 350, 470, 540, 570, 702, 748) from the cylindrical member (14, 54, 80, 400, 420, 500, 572, 574, 752) through the opening.

The implanter (200, 700, 736) can also include a body portion (706) from which a cylindrical enclosure (208, 353, 704, 734) extends and terminates in the open end. See Fig. 19 and page 26, lines 29-31.

A handle portion (712) can be attached to the body portion (706) at a substantially opposite end from which the cylindrical enclosure (208, 353, 704, 734) extends. See Fig. 19 and page 27 lines 14-16.

h. Claim 60 (Depends from Claim 50)

The heart valve (10, 50, 100, 202, 300, 350, 470, 540, 570, 702, 748) can comprise a natural tissue pulmonic animal heart valve. See page 6, lines 4-7; page 20, lines 10-11; page 23, lines 4-5; page 25, lines 11-12.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

a. Whether the rejection of independent claim 18 and dependent claims 54 and 56 as being obvious over U.S. Pat. No. 5,855,601 to Bessler et al. is proper.

b. Whether the rejection of dependent claim 17 as being obvious over U.S. Pat. No. 5,855,601 to Bessler et al. in view of U.S. Pat. No. 5,549,665 to Vesely et al. is proper.

c. Whether the rejection of Independent claim 50 and dependent claims 55 and 60 as being obvious over U.S. Pat. No. 5,855,601 to Bessler et al. in view of U.S. Pat. No. 5,733,267 to Del Toro is proper.

7. ARGUMENT

a. The rejection of independent claim 18 and dependent claims 54 and 56 as being obvious over U.S. Pat. No. 5,855,601 to Bessler et al. is improper.

i. The rejection of claim 18

Claim 18 recites a heart valve prosthesis in combination with an implanter. The heart valve prosthesis includes a generally cylindrical support and a pulmonic valve mounted within the support to define a supported valve. The support extends between opposed ends thereof and a plurality of support features extend generally axially between the opposed ends of the support, which features are interconnected so as to b7ias the support radially outwardly. The supported valve is deformable between a first condition and a second condition. The supported valve has a cross-sectional dimension in the second condition that is less than a cross-sectional dimension of the supported valve when in first condition, whereby implantation of the supported valve is facilitated when in the second condition. The implanter includes an elongated cylindrical

enclosure dimensioned and configured to receive the prosthesis when in the second condition. The prosthesis is disposed within the cylindrical enclosure, such that an inner sidewall of the cylindrical enclosure maintains the prosthesis in the second condition.

Claim 18 stands rejected as being obvious over U.S. Pat. No. 5,855,601 to Bessler et al. ("Bessler et al."). The M.P.E.P. sets forth the criteria for a rejection for obviousness as follows:

> To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure.

See, MPEP § 706.02(j) *citing* In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). It is respectfully suggested that the Office Action fails to establish a prima facie of obviousness with regard to claim 18 in view of Bessler et al. for at least the following reasons:

Significantly, the Office Action admits that Bessler et al. fails to disclose the use of a pulmonic animal heart valve, as recited in claim 18. Without the benefit of any prior art teaching or suggestion, the Office Action then concludes that it would have been obvious matter of design choice to modify the type of valve used in Bessler et al. to a pulmonic valve. In the Advisory Action dated July 26, 2004, the Office Action erroneously asserts that Appellant is relying on features not claimed. This assertion is not correct since Appellant's prior mention of these "features" did not argue disclosed

but unclaimed features, as appears to be suggested in the Advisory Action. Instead, the Appellant's prior statements about the claimed pulmonic valve identified advantages associated with the claimed structure, which includes a pulmonic valve.

Specifically, the heart valve prosthesis and implanter combination recited in claim 18 includes a particular type of heart valve, namely a pulmonic valve. The pulmonic valve corresponds to a heart valve that separates the right ventricle from the pulmonary artery in an animal. Appellant has recognized problems in the current state of the art, including the valves disclosed in Bessler et al., which problems can be mitigated by employing a pulmonic valve in the combination of claim 18. While Bessler et al. notes there is a significant occurrence of re-operation to replace defective heart valves, its main object of Bessler et al. is to provide a minimally invasive technique to facilitate the re-operation. Bessler et al. at Col. 1, lines 34-40, and Col. 2, lines 26-50. Accordingly, the teaching emphasized by Bessler et al. is the non-invasive implantation of a self-expanding heart valve prosthesis, which includes a manufactured type of heart valve that is implanted via catheter. Bessler et al. at Col. 2, lines 26-50. However, the main approach taught by Bessler et al., while it might facilitate re-operation, it fails to address another significant problem. Appellant has recognized that another major problem is the occurrence of re-operation to replace a defective valve, which Appellant seeks to solve by the structure recited in claim 18.

Appellant has determined that a pulmonic valve has inherent structural and functional features (*e.g.*, generally soft and substantially thin cusps), which, for certain applications, including in the combination of claim 18, has a propensity for improved valve function and longevity, when compared to many other types of valves, including

the manufactured valve disclosed in Bessler et al. These advantages, which are indicia of unexpected results, help demonstrate non-obviousness of claim 18 over Bessler et al. The Court of Appeals for the Federal Circuit mandates that such advantages must be considered in an obviousness analysis. *In re Chu,* 34 U.S.P.Q.2d 1089 (Fed Cir 1995). Even though Bessler discloses that an aortic valve can be utilized in the prosthesis (Bessler et al., at Col. 6, lines 20-21), this suggestion, by failing to mention pulmonic, further demonstrates a lack of appreciation for the benefits and advantages associated with utilizing a pulmonic valve in combination with an implanter, as recited in claim 18. For example, an aortic valve includes coronaries and generally has thicker leaflets than a pulmonic valve which would likely inhibit the ability of an aortic valve to be mounted in the stent of Bessler et al. and mounted within an implanter for implantation, as recited in claim 18.

The absence of any teaching of employing a pulmonic valve in the type of heart valve prosthesis used in combination with an implanter, as recited in claim 18, further weighs on the side of non-obviousness, as it demonstrates the failure of those skilled in the art to appreciate the potential benefits of using a pulmonic valve in the combination of claim 18. See, for example, *Arkie Lures Inc. v. Gene Larew Tackle Inc.*, 43 U.S.P.Q.2d 1294, 1297 (Fed. Cir. 1997), where the Court held that when elements have co-existed for many years and never combined weighs on the side of non-obviousness. Similar to the situation in *Arkie Lures*, supra., the combination recited in claim 18 further represents a solution to a problem (an easily implanted, competent heart valve prosthesis) for which there is long felt but unmet need. This becomes clearer when the

teachings of Bessler et al. are considered as a whole which emphasizes a heart valve prosthesis having a manufactured type of valve.

The Final Office Action further asserts that one of ordinary skill in the art "would have expected Appellant's invention to perform equally well with the type of valve chosen as taught by Bessler such that it corresponds to the one being replaced or the claimed pulmonic valve in claim(s) 18 because both heart valve prostheses perform the same function..." Final Office Action dated April 27, 2004, at page 3, lines 6-10. The Examiner has failed to identify a legal basis (statute, rule or legal precedent) to support how the expectation of one skilled in the art about the performance of the combination recited in claim 18, if the structure of claim 18 were modified to use a valve taught by Bessler et al., would affect patentability of claim 18. In addition to there being no factual support for this seemingly erroneous conclusion of law, it appears contrary to the guarantee of objectivity in determining obviousness.

The Advisory Action further contends that "there is nothing in claim 18 to differentiate that the cylindrical member of Bessler could not accommodate a pulmonic valve." Advisory Action, July 26, 2004, at page 2. No statement of law has been provided to support any relevance of whether the cylindrical member of Bessler et al. might be able to accommodate a pulmonic valve. The inquiry should instead focus on whether Bessler et al., when considered as a whole, contains a teaching or suggestion of using a pulmonic valve in the combination recited in claim 18. *In re Lueders*, 42 U.S.P.Q.2d 1481, (Fed. Cir. 1997). When Bessler et al. is considered as a whole, the only proper conclusion is that claim 18 should be patentable.

Further, to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art. MPEP 2144.06. However, what constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case. In re Ruff, 256 F.2d 590, 118 U.S.P.Q. 340 (1958). The mere fact that ingredients may be interchangeable for one purpose does not establish in of itself obviousness. Smith v. Hayashi, 209 U.S.P.Q. 754 (Bd. of Pat. Inter. 1980). Thus, in the instant case, where the proper context is implantation of an expandable type of heart valve prosthesis, the Examiner speculates that a pulmonic heart valve would be equivalent to the type of heart valve taught by Bessler et al. (*i.e.*, manufactured type of valve or an aortic valve).

Without any factual basis for support, the Office Action's statements are merely speculation. "Speculation is not sufficient for establishing a prima facie case of obviousness... a rejection based on §103, must rest upon a factual basis rather than conjecture, or speculation." Ex Parte Yamamoto, 57 U.S.P.Q.2d 1382, 1383 (B.P.A.I. 2001); citing In re Warner, 379 F.2d 1011, 1017, 154 U.S.P.Q. 173, 178 (CCPA 1967).

Finally, as in *In re Lueders*, supra., the Examiner has offered no factual evidence to support its finding that one skilled in the art would be able to combine the teachings of a Bessler et al. as a whole to form the combination recited in claim 18. Since no factual basis has been offered to provide motivation to use a pulmonic valve in the combination of claim 18, the contention in the Office Action appears to rely on improper hindsight to support an obviousness conclusion of claim 18, essentially stating that it would be obvious to create the combination or claim 18 since Appellant claims it.

ii. **The rejection of claim 54**

In addition to the combination of implanter and heart valve prosthesis recited in claims 18 and 53, claim 54 further recites that the cylindrical enclosure of the implanter has an inner diameter in a range from about 5 mm to about 15 mm, and that the body portion of the implanter has a diameter that is greater than that of the cylindrical enclosure. Since this feature of the implanter is independent of the combination recited in claim 18, claim 54 stands alone.

Additionally, Bessler et al. does not disclose an implanter having a body portion from which the cylindrical enclosure extends and which body portion has a diameter that is greater than the enclosure in which the heart valve prosthesis is disposed. Significantly, the Office Action fails to identify any structure shown in described in Bessler et al. that might correspond to the particular claimed structural relationship between and the dimensions of the enclosure and the body portion. It is submitted that such silence in the Office Action is because Bessler et al. contains no teaching or suggestion that a body portion of an implanter would have a diameter that is greater than that of the cylindrical enclosure. In sharp contrast, Bessler et al. discloses only a catheter type of implanting device, which has wall that appears (see Figures 12-15 of Bessler et al.) to have a substantially constant diameter and no apparent body portion, as recited in claim 54.

iii. **The rejection of claim 56**

In addition to the combination of implanter and heart valve prosthesis recited in claims 18 and 53, claim 56 recites that the cylindrical enclosure and body portion of the implanter are substantially coaxial along a linear axis extending through the implanter

(See, *e.g.*, Figure 19 of the instant application). Since the claimed coaxial relationship of the enclosure and body portion of the implanter is independent of the combination recited in claim 18, claim 56 also stands alone.

In addition to Bessler et al. failing to disclose the body portion recited in claim 53, from which claim 56 depends, Bessler et al. also fails to disclose the coaxial relationship between the body portion and the cylindrical enclosure relative to a linear axis, as recited in claim 56. Specifically, no linear axis would seem to exist in the implanting device, namely the catheter, shown and described in Bessler et al. Since there is no body portion and no linear axis in the curved, flexible sidewall of the implanting device taught by Bessler et al., there further cannot be a coaxial relationship between the body portion and enclosure in which the prosthesis is disposed, as recited in claim 56.

b. The rejection of dependent claim 17 as being obvious over U.S. Pat. No. 5,855,601 to Bessler et al. in view of U.S. Pat. No. 5,549,665 to Vesely et al. is improper.

i. <u>The rejection of claim 17</u>

Claim 17 depends from independent claim 18 and further recites that the prosthesis further comprises an outer sheath of a substantially biocompatible material that covers the exposed parts of the support.

In addition to the reasons stated above with respect to claim 18, neither Bessler et al. or Vesely et al. teaches that an outer sheath of a substantially biocompatible material that covers exposed parts of a support in which a pulmonic valve is mounted. It is respectfully submitted that covering the artificial heart valve of Bessler et al. with the covering of Vesely et al. appears contrary to the teachings of Bessler et al., which, as a

whole, teaches a minimal valve structure so that it can be collapsed into a catheter for implantation. For instance, the use of a cloth covering, as taught by Vesely et al., likely would significantly compromise the ability to collapse the valve into a small cylinder so that it can be implanted by a catheter, as taught by Bessler et al. Accordingly, there is a lack of motivation for one skilled in the art to employ the cloth covering taught by Vesely et al. in the valve of Bessler et al.

1. There is not proper motivation to combine Bessler et al. and Vesely et al.

Moreover, the combination of Bessler et al. and Vesely et al. appears improper. Specifically, Vesely et al. is directed to a heart valve prosthesis that includes an animal leaflet valve mounted to support structure that includes a rigid support ring and a flexible stent post ring (See, Vesely et al. at Col. 3, lines 40-43, Col 4, lines 13-18). A cloth cover is sewn to the animal leaflet valve or it can be sewn to both the valve and the stent posts (See, Vesely et al. at Col 4, lines 17-20). In contrast to the rigid type of support taught by Vesely et al., Bessler, et al. is directed to a flexible type of prosthesis that is manufactured from a self-expanding stent and a flexible valve means so that the prosthesis can be implanted via a catheter. When each of the Vesely et al. and Bessler, et al. patents is considered as a whole, the divergent teachings fail to provide sufficient motivation to cause one skilled in the art to combine such teachings.

Furthermore, the Office Action fails to cite any reason or motivation for combining Bessler et al. and Vesely et al. It is submitted that the suggested combination of Bessler et al. and Vesely et al. seems plausible only using hindsight after having the benefit of the Appellant's disclosure then searching for a reference that discloses some type of outer sheath. It is well settled, however, that the use of the teachings of the

present invention to find obviousness is not permissible. "It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In Re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). Thus, it is respectfully suggested that there is no suggestion or motivation for combining Bessler et al. and Vesely et al.

c. The rejection of Independent claim 50 and dependent claims 55 and 60 as being obvious over U.S. Pat. No. 5,855,601 to Bessler et al. in view of U.S. Pat. No. 5,733,267 to Del Toro is not proper.

i. <u>The rejection of claim 50</u>

An amendment to claim 50 is submitted herewith as Appendix B. The amendment seeks to correct a typographical error in claim 50 by deleting a second recitation of a "body portion" and inserting the word "to" in line 13 thereof. The errors were made in an amendment filed on January 20, 2004, in response to a non-final Office Action dated October 22, 2003. The amendment of January 20, 2004, sought to rewrite claim 50 in independent form, but inadvertently introduced the above-noted errors. The amendment to claims 50 and 53 were previously presented in a response filed on June 28, 2004 in response to the final Office Action dated April 27, 2004. However, the amendments to claims 50 and 53 were not entered by the Examiner.

Appellant submits that the amendments to claims 50 and 53 should be entered for purposes of appeal since it will greatly simplify resolution of this matter on appeal. No showing under 37 C.F.R. 1.116 is required since the amendment corrects typographical errors noted by the Examiner in the Final Office Action dated April 27,

2004 and in an Advisory Action dated July 26, 2004. Therefore, review and entry of the amendments should only require a cursory review by the Examiner.

For purposes of the following discussion so as to facilitate resolution on appeal, Appellant will assume entry of the amendment to claim 50, which is set forth in Appendix B.

Claim 50 recites an implantation system that includes an elongated cylindrical member having spaced apart ends, at least one of the ends providing an opening. The system includes a body portion from which the cylindrical member extends to terminate in the opening spaced apart from the body portion. A heart valve prosthesis includes a generally cylindrical support having axially spaced apart ends. A valve is mounted within the support at a fixed axial position between the spaced apart ends of the support. The prosthesis is deformable to a first condition in which the prosthesis has a reduced cross-sectional dimension. The support is biased to expand the prosthesis radially outwardly from the first condition to a second condition in which the prosthesis has a cross-sectional dimension that greater than reduced cross-sectional dimension. The prosthesis is mounted within the cylindrical member in the first condition. A plunger is operative to traverse at least part of the cylindrical member and urge the prosthesis from the cylindrical member through the opening. A handle portion is attached to the body portion at a position near a substantially opposite end of the body portion from which the cylindrical member extends.

1. There is not proper motivation to combine Bessler et al. and U.S. Pat. No. 5,733,267 to Del Toro ("Del Toro").

First, the Office Action is silent on any motivation to combine the teachings of Bessler et al. and Del Toro. The Office Action simply concludes that "[i]t would have been obvious to one of ordinary skill in the art to use a handle as taught by Del Toro with the delivery device of Bessler such that the surgeon can accomplish accurate control of the delivery device." However, when the teaching of Del Toro is considered as a whole, as is required, the lack of motivation to combine the teachings of Del Toro with those of Bessler becomes evident.

As mentioned above, Bessler relates to catheter implantation of a heart valve prosthesis that includes a valve disposed within a self-expanding stent. In contrast, Del Toro relates to a delivery system for a stent that does not include a valve. As shown and described with respect to FIGS. 4 and 5 of Del Toro, the delivery system 30 includes three shaft portions, an inner shaft 36, a middle shaft 34 and an outer shaft 32. A manifold stabilizer 40, which the Office Action purports corresponds to the handle recited in claim 50, is connected to space apart the outer shaft 32 a predetermined distance from the inner shaft 36. Specifically, Del Toro states that "[i]t is important that the two shafts are connected together far enough apart to provide enough room for the middle pull back shaft to be fully retracted to completely release the stent 38 to self-expand, as shown in FIG. 5." Del Toro, at Col. 3, lines 17 – 22.

The delivery system of Del Toro, which includes the manifold stabilizer 40, is substantially different in function and structure from that taught by Bessler et al. so that there is not proper motivation to employ the manifold stabilizer 40 in the catheter implantation of a heart valve prosthesis taught by Bessler et al. As mentioned above, in

the delivery system of Del Toro, the inner shaft 36, which is connected to the manifold stabilizer 40, extends through the stent 38, and is urged off of the inner shaft 36 by pulling the middle shaft 34 toward the end of outer shaft 32, which is maintained spaced apart from the inner shaft by the manifold stabilizer 40. Del Toro at Col. 3, lines 23 – 27. Such an approach would be inoperative with the heart valve implantation taught by Bessler et al. since insertion of the inner shaft through the heart valve likely would destroy the function of the valve.

Moreover, to incorporate the manifold stabilizer 40 from Del Toro apart from its purpose in the delivery system for which it is intended would be contrary to the teachings of Del Toro. In view of the foregoing significant differences between the teachings of Bessler et al. and Del Toro, it is respectfully submitted that the combination of Del Toro with Bessler et al. appears to be based on improper hindsight in which the Office Action is attempting to impermissibly extract features out of the context in which they were intended. See, *In Re Fritch*, supra.

ii. <u>The rejection of claim 55</u>

Claim 55 depends from claim 18. Thus, claim 55 is patentable for its recitation of a pulmonic animal heart valve for the reasons stated above with respect to claim 18 as well as for its recitation of a handle for the reasons stated above with respect to claim 50.

iii **The rejection of claim 60**

Claim 60 is separately patentable from claim 50. The separate patentability arises since claim and 60 further recites that the heart valve further comprises a natural tissue pulmonic animal heart valve, wherein claim 50 does not require any particular type of valve. The additional recitation of the pulmonic heart valve provides an independent basis for the patentability of 60 from that of claim 50.

Similarly, in addition to the reasons stated above with respect to claim 50, claim 60 should further be allowable patentable for its recitation of a pulmonic animal heart valve for at least the reasons stated above with respect to claim 18. With respect to claim 60, the Office Action contends that "[i]t would have been an obvious matter of design choice to modify the type of valve used, since applicant has not disclosed that using a pulmonic valve provides any advantage, or solves a stated problem, or is used for any particular purpose." Appellant has previously identified of advantages in a response as well as above with respect to claim 18. The Court of Appeals for the Federal Circuit mandates such advantages must be considered. See *In re Chu*, supra. Moreover, the contention by the Examiner is without merit since no statute or federal rules require that an applicant disclose that a claimed structure provides an advantage, or solves a stated problem, or is used for any particular purpose. The fact that such features are claimed and are not taught or suggested in the prior art for use in an implantation system for implanting the type of valve set forth in claim 60 and other claims weighs on the side of non-obviousness. Notwithstanding the foregoing, the specification states that the valve provides desired functionality and coaptation of the

valve when it is implanted (Page 2, lines 27-30) as well as identifies other advantages of the claimed structures.

d. Conclusion

In view of the foregoing, Appellant respectfully submits that claims 2–19, 28, 53-57 and 60 are allowable. Reversal of the rejection is respectfully requested.

8. APPENDICES

Appendix A submitted herewith is a claims appendix containing a copy of the claims on appeal.

Appendix B submitted herewith is a copy of an amendment that is being filed for purposes of this appeal.

Appendix C submitted herewith is an evidence appendix.

Appendix D submitted herewith is a related proceedings appendix.

In the event any fees are due in connection with the filing of this document, including for any extensions of time, the Commissioner is authorized to charge those fees to our Deposit Account No. 20-0090.

Respectfully submitted,

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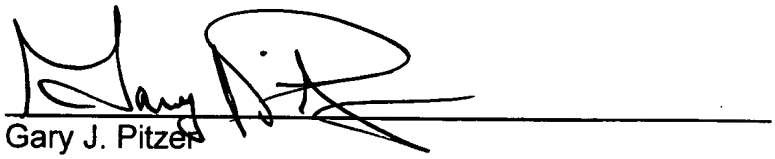

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Appendix A (Claims Appendix)

2. The combination of claim 18, the prosthesis further comprising biasing elements that interconnect at least some of the support features, each biasing element urging support features that are interconnected by respective biasing element apart from each other.

3. The combination of claim 2, the biasing elements further comprising springs arranged in a generally circular array at the opposed ends of the support, the springs interconnecting adjacent support features to bias the support radially outwardly.

4. The combination of claim 3, the support features and the springs of the prosthesis being formed of a continuous length of a resilient material to provide a cage-like support.

5. The combination of claim 3, the prosthesis further comprising projections biased to extend radially outwardly from at least one of the opposed ends.

6. The combination of claim 5, the projections of the prosthesis further comprising a set of triangular projections interconnected at the opposed ends by biasing elements that orient the triangular projections to extend axially and radially outwardly from the respective opposed ends.

7. The combination of claim 18, the prosthesis further comprising a flexible connecting element attached to the support to inhibit radial outward expansion of at least part of the support beyond a predetermined amount.

8. The combination of claim 7, the connecting element of the prosthesis further comprising a loop of a flexible cord.

9. The combination of claim 7, the prosthesis further comprising a loop of a flexible material connected to the support at each of the opposed ends to inhibit radial outward expansion of the support at the opposed ends beyond a predetermined amount.

10. The combination of claim 18, the support of the prosthesis further comprising at least two generally cylindrical support portions having adjacent ends connected substantially coaxially together, the support portions also having respective spaced apart ends that define the axially opposed ends of the support, the valve including an inflow end and an outflow end spaced apart from each other on axially opposed sides of a juncture between the support portions.

11. The combination of claim 10, the prosthesis further comprising an intermediate connecting element that connects the support portions at the juncture between the support portions.

12. The combination of claim 10, each of the support portions of the prosthesis having a sidewall portion comprising a plurality of elongated support features that extend generally axially between the ends of each respective support portion in a circumferential arrangement, the support features of each support portion being interconnected so as to bias each respective sidewall portion and the valve mounted therein radially outwardly.

13. The combination of claim 12, the prosthesis further comprising a plurality of biasing elements that interconnect adjacent support features in each of the support portions, the biasing elements urging the interconnected support features apart from each other to provide radial outward expansion of the respective sidewall portions.

14. The combination of claim 13, the biasing elements of the prosthesis being connected by flexible connecting elements in a generally circular arrangement at the ends of each respective support portion, the connecting elements inhibiting radial

expansion of at the respective ends of the support portions beyond a predetermined amount.

15. The combination of claim 12, the prosthesis further comprising projections biased to extend radially outwardly from the axially opposed ends of the support.

16. The combination of claim 15, the projections of the prosthesis further comprising a set of triangular projections connected at each of the opposed ends by biasing elements that bias the triangular projections to extend axially and radially outwardly from the respective opposed ends.

17. The combination of claim 18, the prosthesis further comprising an outer sheath of a substantially biocompatible material that covers the exposed parts of the support.

18. A heart valve prosthesis in combination with an implanter, the combination comprising:

the heart valve prosthesis comprising:

a generally cylindrical support extending between opposed ends thereof, a plurality of support features extend generally axially between the opposed ends of the support and are interconnected so as to bias the support radially outwardly; and

a pulmonic valve mounted within the support to define a supported valve, the supported valve being deformable between a first condition a second condition, the supported valve having a cross-sectional dimension in the second condition that is less than a cross-sectional dimension of the supported valve when in first condition, whereby implantation of the supported valve is facilitated when in the second condition;

the implanter including an elongated cylindrical enclosure dimensioned and configured to receive the prosthesis when in the second condition; and

the prosthesis being disposed within the cylindrical enclosure, such that an inner sidewall of the cylindrical enclosure maintains the prosthesis in the second condition.

19. The combination of claim 18, the implanter further comprising a plunger operative to move within the cylindrical enclosure and urge the prosthesis out of the cylindrical enclosure, the support being operative to expand the prosthesis from the second condition to the first condition when discharged from the cylindrical enclosure.

20. An implantation system, comprising:

an elongated cylindrical member having spaced apart ends, at least one of the ends providing an opening;

a body portion from which the cylindrical member extends to terminate in the opening spaced apart from the body portion, the body portion having a greater outer diameter than the cylindrical member;

a heart valve prosthesis including a generally cylindrical support having axially spaced apart ends, a valve mounted within the support at a fixed axial position between the spaced apart ends of the support, the prosthesis being deformable to a first condition in which the prosthesis has a reduced cross-sectional dimension, the support being biased to expand the prosthesis radially outwardly from the first condition to a second condition in which the prosthesis has a cross-sectional dimension that greater than reduced cross-sectional dimension, the prosthesis being mounted within the cylindrical member in the first condition; and

a plunger operative traverse at least part of the cylindrical member and urge the prosthesis from the cylindrical member through the opening.

21. The system of claim 20, the support being formed of a shape memory alloy operative to urge the prosthesis to the second condition.

22. The system of claim 20, the support further comprising a plurality of elongated support features that extend generally axially between ends of the support,

biasing elements interconnecting adjacent support features in a circumscribing relationship around the valve, the biasing elements urging the interconnected adjacent support features apart from each other, so as to urge the prosthesis toward the second condition.

23. The system of claim 22, further comprising at least one connecting element operative to hold the biasing elements in a generally circular array and to limit the radial outward expansion of the prosthesis at the location of the circular array.

24. The system of claim 22, further comprising a plurality of resilient projections that extend radially outwardly from the axially opposed ends of the support.

25. The system of claim 24, the projections further comprising a set of triangular projections attached to each of the opposed ends of the support by biasing elements that bias the triangular projections to extend axially and radially outwardly from each of the respective opposed ends of the support.

26. The system of claim 22, the support features and the biasing elements being formed of a continuous length of a substantially resilient and elastic material that facilitates expansion of the prosthesis from the first condition to the second condition.

27. The system of claim 20, further comprising an outer sheath of a substantially biocompatible material that covers the exposed parts of the support.

28. The system of claim 20 wherein the valve further comprises a pulmonic animal heart valve having leaflets located within a valve wall to permit substantially unidirectional flow of blood through the valve, the support engaging an outer surface of the valve wall.

49. The system of claim 20, the cylindrical member having an inner diameter in a range from about 5 mm to about 15 mm, and the body portion having a diameter that is greater than that of the cylindrical member.

50. An implantation system, comprising:

an elongated cylindrical member having spaced apart ends, at least one of the ends providing an opening;

a body portion from which the cylindrical member extends to terminate in the opening spaced apart from the body portion;

a heart valve prosthesis including a generally cylindrical support having axially spaced apart ends, a valve mounted within the support at a fixed axial position between the spaced apart ends of the support, the prosthesis being deformable to a first condition in which the prosthesis has a reduced cross-sectional dimension, the support being biased to expand the prosthesis radially outwardly from the first condition to a second condition in which the prosthesis has a cross-sectional dimension that greater than reduced cross-sectional dimension, the prosthesis being mounted within the cylindrical member in the first condition;

a plunger operative traverse at least part of the cylindrical member and urge the prosthesis from the cylindrical member through the opening;

a body portion from which the cylindrical member extends and terminates in the opening; and

a handle portion attached to the body portion at a position near a substantially opposite end of the body portion from which the cylindrical member extends.

51. The system of claim 49, the cylindrical member and body portion being substantially coaxial along a linear axis extending through the implanter.

52. The system of claim 51, further comprising indicia along an exterior portion of the cylindrical member to facilitate implantation of the heart valve prosthesis.

53. The combination of claim 18, the implanter further comprising a body portion from which the cylindrical enclosure extends and terminates in the open end.

54. The combination of claim 53, the cylindrical enclosure of the implanter having an inner diameter in a range from about 5 mm to about 15 mm, and the body portion having a diameter that is greater than that of the cylindrical enclosure.

55. The combination of claim 53, the implanter further comprising a handle portion attached to the body portion at a substantially opposite end from which the cylindrical enclosure extends.

56. The combination of claim 53, the cylindrical enclosure and body portion of the implanter being substantially coaxial along a linear axis extending through the implanter.

57. The combination of claim 56, the implanter further comprising indicia along an exterior portion of the cylindrical enclosure to facilitate implantation of the heart valve prosthesis.

60. The implantation system of claim 50, the heart valve further comprising a natural tissue pulmonic animal heart valve.